

January 17, 2005

REMARKS

Status of the Claims

Claims 1, 33 and 36 have been amended. Claims 2-32, 34, 35, 37 and 38 have been cancelled. Claim 39 has been added. Accordingly, there is presented for the Examiner's consideration Claims 1, 33, 36, and 39.

Summary of the Claim Rejections

Claims 1, 3, 6, 7, 28, 30, 32, and 35-38 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the rejection under 35 U.S.C. § 112, first paragraph, is based on the recitation of methacrylic acid which, according to the Examiner, is not disclosed in the specification.

Claims 32, 35 and 37 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applications regard as the invention. Specifically, the rejection under 35 U.S.C. § 112, second paragraph, is based on claims 32 and 35 which, according to the Examiner, depend from canceled claim 27.

Claims 1, 6, 7, 28, 30, 35, 37 and 38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,603,947 to Wong et al. ("the '947 patent") in view of U.S. Patent No. 5,914,282 to Dunshee et al. ("the '282 patent").

The Examiner has further indicated that claims 3, 32, 33 and 36 would be allowable if rewritten to overcome the rejections(s) under 35 U.S.C. § 112, and to include all of the limitations of the base claim and any intervening claims.

January 17, 2005

Summary of Applicants' Invention

Applicants' invention is summarized in the Reply that was filed on March 15, 2002. As reflected in claims 1 and 39, two features which distinguish applicants' transdermal patch over the prior art are: (i) a solid silicone adhesive layer which contains a normally volatile drug (for example, nicotine) and which is a source in the patch of the drug; and (ii) a solid acrylic adhesive layer which underlies (viewed from the area of skin contact) the silicone adhesive layer and which is in diffusional contact therewith. The resins comprising these layers and the positioning of the layers in the patch are critical to the effective manufacture of the patch and to its successful functioning.

As to the drug-containing layer, the volatile drug in the patch is contained initially in the layer of silicone adhesive which is highly soluble in a high vapor pressure solvent, for example, hexane. In forming applicants' patch, a layer containing the volatile drug is formed from a solution of the volatile drug, the silicone adhesive, and the high vapor-pressure solvent by casting a film of the solution and evaporating the solvent. The solvent evaporates readily at a relatively low temperature, that is, at a temperature at which loss of the volatile drug is minimized or avoided during the drying process which leads to formation of the solid layer of the drug-containing silicone adhesive. In contrast, the use of an adhesive (as the drug-containing adhesive) which is not highly soluble in a high vapor-pressure solvent and which requires the use of a solvent that has a relatively low vapor pressure (thus, requiring the use of relatively high "evaporating" temperatures) would result in the loss of a substantial amount of the volatile drug during the manufacturing process.

As to the acrylic adhesive layer which underlies the drug-containing silicon adhesive layer, the rate of drug diffusion through the acrylic adhesive is slower than the diffusion rate

January 17, 2005

through a silicone adhesive. Accordingly, there is a controlled diffusion of the drug from the acrylic adhesive layer to the skin over a sustained period of time.

Remarks Regarding Rejection Under § 112, First Paragraph

As noted above, claims 1, 3, 6, 7, 28, 30, 32, and 35-38 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Insofar as claims 3, 6, 7, 28, 30, 32, and 35-38 have been canceled without prejudice, the rejection is moot with respect to such claims. As for the rejection of claim 1, applicants note that the basis for the rejection is a result of a typographical error that was made in the prior amendment to claim 1. Specifically, in amending claim 1 to indicate the components of the copolymer comprising the solid acrylic adhesive layer, reference was made to methacrylic acid rather than acrylic acid. As shown in lines 18-21 on page 5 of the specification, the adhesives of the solid acrylic adhesive layer are “usually copolymers composed of: 50% to 90% of a main acrylate or methacrylate monomer, usually 2-ethylhexyl acrylate, butylacrylate, or iso-octyl acrylate; 10% to 40% of a modifying monomer such as vinyl acetate; and 2% to 20% of a functional group-containing monomer such as acrylic acid.” (Emphasis added). As amended, claim 1 now recites acrylic acid rather than methacrylic acid. Accordingly, claim 1 now satisfies the written description requirement of 35 U.S.C. § 112, first paragraph. Applicants request respectfully that the rejection be withdrawn.

Remarks Regarding Rejection Under § 112, Second Paragraph

As noted above, claims 32, 35 and 37 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Insofar as claims 32, 35 and 37 have

January 17, 2005

been canceled without prejudice, the rejection is moot with respect to such claims. As noted above, the Examiner has indicated that claim 32 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 112, second paragraph, and to include all of the limitations of the base claim which, in this case, is claim 27. In accordance with this suggestion, applicants offer new claim 39 which reinstates canceled claim 27 and incorporates the additional limitations found in claim 32. Accordingly, new claim 39 is equivalent to claim 32 rewritten to overcome the rejection under 35 U.S.C. § 112, second paragraph, and to include all of the limitations of the base claim.

Remarks Regarding Rejection Under § 103

As noted above, claims 1, 6, 7, 28, 30, 35, 37 and 38 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the '947 patent in view of the '282 patent. While applicants respectfully disagree with the reasoning as presented in the most recent Office Action, applicants have nonetheless canceled without prejudice claims 6, 7, 28, 30, 35, 37 and 38 in order to facilitate prosecution of this application. Applicants reserve the right to pursue these claims further in a continuation application.

With respect to this rejection as applied to claim 1, applicants have amended claim 1 to include the additional limitations found in claim 3 in which the drug is specified as a combination of nicotine and mecamylamine and the patch is specified as capable of administering 0.2 to 1.5 mg nicotine per hour and 0.02 to 1 mg mecamylamine per hour to the patient. As noted above, the Examiner has indicated that claim 3 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 112 and to include all of the limitations of the base claim which, in this case, is claim 1. By amending claim 1 to include the recitation of the additional limitations of claim 3 and to correct the typographical error from

January 17, 2005

methacrylic acid to acrylic acid, applicants have effectively rewritten claim 3 in accordance with the Examiner's suggestion. Accordingly, applicants request respectfully that the rejection based on 35 U.S.C. §103(a) be withdrawn.

With respect to claims 33 and 36, applicants have amended these claims also in accordance with the Examiner's suggestion. Specifically, claim 33 previously depended from claim 28 which, in turn, depended from claim 1. In view of the amendment to claim 1, which now includes the additional limitations of claim 3, claim 33 has been amended to depend from claim 1 and include the additional limitations of claim 28. Claim 36, which previously depended from claim 3, has been amended to depend from claim 1 which, as noted above, now includes the additional limitation of claim 3. Accordingly, claims 33 and 36 have been rewritten to overcome the rejection under 35 U.S.C. § 112 and to include all of the limitations of the base claim and any intervening claims.

In view of the amendments and remarks set forth above, it is requested respectfully that the Examiner withdraw all outstanding rejections and allow the application as now amended in an early and favorable action.

Respectfully submitted,



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